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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER	
LEITH, PATRICIA A	

ART UNIT	PAPER NUMBER
1655	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/521,380	MCARTHUR, THOMAS JAMES	
	Examiner	Art Unit	
	Patricia Leith	1655	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-11* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-11* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *1/6/06*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Claims 1-11 are pending in the application and were examined on their merits.

Claim Rejections - 35 USC § 101

35 U.S.C. 101 reads as follows:

> Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claims 8 and 9 are rejected under 35 U.S.C. 101 because the claimed recitation of a use, without setting forth any steps involved in the process, results in an improper definition of a process, i.e., results in a claim which is not a proper process claim under 35 U.S.C. 101. See for example *Ex parte Dunki*, 153 USPQ 678 (Bd.App. 1967) and *Clinical Products, Ltd.* v. *Brenner*, 255 F. Supp. 131, 149 USPQ 475 (D.D.C. 1966).

Claims 8 and 10 are rejected under 35 U.S.C. 101 because these claims are broad enough to read on prevention of skin cancer. 'Prevention' of cancer is deemed to be a 'cure' since prevention would cease the condition of cancer from occurring. To date, there is no 'cure' for cancer, and the specification does not set forth any reasonable expectation that any compositions disclosed will prevent or even treat cancer.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 8 and 9 provides for the use of the composition of claim 6, but, since the claim does not set forth any steps involved in the method/process, it is unclear what method/process applicant is intending to encompass. A claim is indefinite where it merely recites a use without any active, positive steps delimiting how this use is actually practiced.

Claims 1-11 either recite, or depend upon a claim which recites 'heating a fruit and/or vegetable pulp' or 'vegetable derived composition' or is a method for using the composition which states 'fruit and/or vegetable derived composition.' is deemed that Applicant has not set forth a representative number of examples in order to reasonably verify possession of such a potentially enormous number fruits and/or vegetable products.

The MPEP states that written description for a genus can be achieved by a representative number of species within a broad generic. It is unquestionable that the claims are broad generics, with respect to *all* fruits and/or vegetables. The possible variations of products are limitless. Although Applicant has disclosed several types of fruits and/or vegetables as listed on page 4 of the Instant specification, this disclosure is actually a *very few* number in comparison to the enormous types of fruits and vegetables actually known.

The MPEP states that the purpose of the written description requirement is to ensure that the invention had possession, as of the filing date of the application, of the specific subject matter later claimed by him or her. The courts have stated:

"To fulfill the written description requirement, a patent specification must describe an invention and do so in sufficient detail that one skilled in the art can clearly conclude that the inventor invented the claimed invention.' Lockwood v. American Airlines, Inc., 107 F. 3d 1565, 1572, 41 USPQ2d 1961, 1966 (Fed. Cir. 1997); In re Gostelli, 872 F. 2d 1008, 1012, 10 USPQ2d 1614, 1618 (Fed. Cir. 1989) ("[T]he description must clearly allow persons of ordinary skill in the art to recognize that [the inventor] invented what is claimed."). Thus, an applicant complies with the written description requirement "by describing the invention, with all its claimed limitations, no that which makes it obvious," and by using "such descriptive means as words, structures, figures, diagrams, formulas, etc., that set forth the claimed invention." Lockwood, 107 F. 3d at 1572, 41 USPQ2d at

1966." Regents of the University of California v. Eli Lilly & Co., 43 USPQ2d 1398. The specification lacks sufficient variety fruits and vegetables to reflect this variance in the genus since the specification does not provide sufficient examples of such a genus of fruits and vegetables

The description requirement of the patent statue requires a description of an invention, not an indication of a result that one might achieve if one made that invention. See *In re Wilder*, 736, F. 2d 1516, 1521, 222 USPQ 369, 372-73 (Fed. Cir. 1984) (affirming rejection because the specification does "little more than outline [goals] appellants hope the claimed invention achieves and the problems the invention will hopefully ameliorate.") Accordingly, it is deemed that the specification fails to provide adequate written description for the genus of 'fruits and vegetables' and does not reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed had possession of the entire scope of the claimed invention and thus, this rejection is proper.

Claims 8-11 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a method for treating psoriasis, scars or pain topically with a composition comprising pawpaw fruit prepared according to the process indicated on pages 35-36 of the Instant specification, does not reasonably provide enablement for treating or preventing any dermatological disorders or treating pain, or where any vegetable/fruit matter is used. The specification does not enable any person

skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with these claims.

The factors to be considered in determining whether undue experimentation is required are summarized In re Wands 858 F.2d 731, 8 USPQ2nd 1400 (Fed. Cir, 1988). The court in Wands states: "Enablement is not precluded by the necessity for some experimentation such as routine screening. However, experimentation needed to practice the invention must not be undue experimentation. The key word is 'undue,' not 'experimentation.' " (Wands, 8 USPQ2d 1404). Clearly, enablement of a claimed invention cannot be predicated on the basis of quantity of experimentation required to make or use the invention. "Whether undue experimentation is needed is not a single, simple factual determination, but rather is a conclusion reached by weighing many factual considerations." (Wands, 8 USPQ2d 1404). The factors to be considered in determining whether undue experimentation is required include: (1) the quantity of experimentation necessary, (2) the amount or direction or guidance presented, (3) the presence or absence of working examples, (4) the nature of the invention, (5) the state of the prior art, (6) the relative skill of those in the art, (7) the predictability or unpredictability of the art, and (8) the breadth of the claims. While all of these factors are considered, a sufficient amount for a *prima facie* case are discussed below.

It is clear that the pawpaw composition is an extract of the pawpaw fruit, which

seems to closely resemble the juice of the pawpaw fruit. The juice is considered an 'extract' of the pawpaw fruit. Applicant has discovered that this juice has pain reducing effects, as well as moisturizing effects (i.e., lessening the effects of psoriasis and scar). While the active ingredients of Applicant's extract have not been elucidated, it is clear that the extract contains some unknown active ingredient.

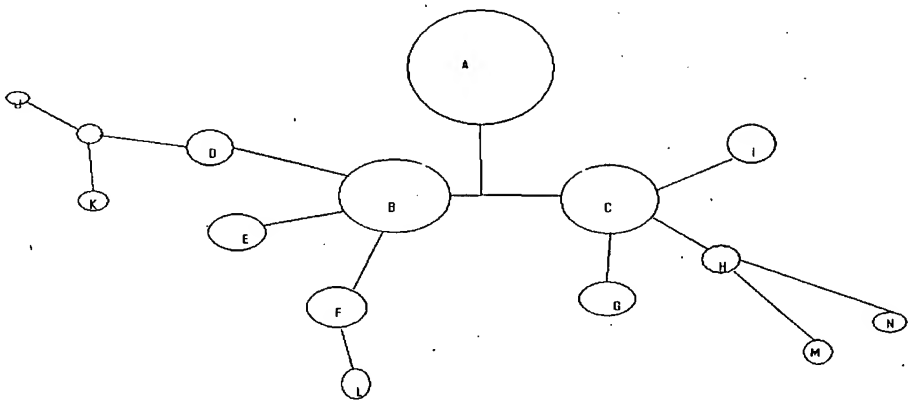
The state of the art is unpredictable with regard to plant extracts. The scope of the required enablement varies inversely with the degree of predictability involved, but even in unpredictable arts, a disclosure of every operable species is not required. A single embodiment may provide broad enablement in cases involving predictable factors, such as mechanical or electrical elements. *In re Vickers*, 141 F.2d 522, 526-27, 61 USPQ 122, 127 (CCPA 1944); *In re Cook*, 439 F.2d 730, 734, 169 USPQ 298, 301 (CCPA 1971). However, in applications directed to inventions in arts where the results are unpredictable, the disclosure of a single species usually does not provide an adequate basis to support generic claims. *In re Soll*, 97 F.2d 623, 624, 38 USPQ 189, 191 (CCPA 1938). In cases involving unpredictable factors, such as most chemical reactions and physiological activity, more may be required. *In re Fisher*, 427 F.2d 833, 839, 166 USPQ 18, 24 (CCPA 1970) (contrasting mechanical and electrical elements with chemical reactions and physiological activity). See also In re Wright, 999 F.2d 1557, 1562, 27 USPQ2d 1510, 1513 (Fed. Cir. 1993*); In re Vaeck*, 947 F.2d 488, 496, 20 USPQ2d 1438, 1445 (Fed. Cir. 1991). This is because it is not obvious from the disclosure of one species, what other species will work (see MPEP § 2164.04)

It is well known in the art that polarity of solvents plays a key role in determining the final product obtained by an extraction. However, because many phytochemicals remain undiscovered, the skilled artisan has to make his best educated guess as to what types of phytochemicals will be successfully extracted with a solvent of a particular polarity. Often times, unless the constituents in a particular plant extract have been well evaluated and documented in the literature, the skilled artisan must adhere to trial and error protocols in order to quantitatively determine phytochemical constituents present in samples obtained from respective extraction procedures. These procedures are common when, for example, a plant or part thereof has been documented in the literature as possessing some medicinal quality. The skilled artisan will attempt numerous extraction protocols in attempt to isolate the particular ingredient which has this medicinal quality. Typically, beginning with the first crude extraction, it is a guess as to weather or not the extract will possess certain phytochemical constituents. It is noted that the Instant specification does not disclose what the active ingredient of the extract is; on the contrary, the specification only teaches certain extracts which provide for the effective ingredient.

Each successive extraction of plant matter yields different products due to the exclusion of ingredients based on the polarity of the solvents solvating constituents with similar polarities. Subsequently, the properties of each respective product are unpredictable and would need to be evaluated for chemical constituents. The following

is an illustrative example of the many products which may be produced by different successive extraction

protocols:



In this example, assume that A= the initial water extract from a homogenized sample of grape. The water extract from the grape is then subjected to a methanol/water extraction to form products B (soluble with methanol) and C (more soluble with water). Product C is then extracted in a seperatory funnel with three organic solvents: chloroform, benzene and ethyl ether to form products G, H and I which solvate with the respective solvents based on the polarity of the inherent constituents. Product H, which we will assume is the product obtained in the benzene fraction, is extracted again in a seperatory funnel with benzene and methanol to remove any

residual methanol-soluble constituents. The additional circles represent extractions which may be done to obtain different products, using similar solvents as discussed previously, or entirely different solvents. Consequently, the characteristics of each respective product would need to be evaluated for chemical constituents. This representation is indicative of the vast array of distinct products which may be obtained due to the ***enormity of possible extraction permutations***.

Unpredictability with regard to plant extracts due to their highly complex nature has been well documented in the art. Revilla et al. for example (1998) showed that the ***slightest variations in polarity of solvent and reaction time*** upon grape extraction provided respective products with unique characteristic properties (See Tables 1, 2, 4, 5, 6 and 7). In turn, each product would possess varying pharmacological properties based upon their respective methods of extraction. Further contributing to the unpredictability of plant extracts, it has been determined that in some cases, the active agent is not a single ingredient, but a combination of ingredients working synergistically to provide a therapeutic effect:

> "The blood red sap from the bark of several species of Croton (Euphorbiaceae) are used in traditional medicine in S. America to treat wounds and a series of diseases including cancer. More than 90% dry weight of the sap consists of mixtures of proanthocyanidins ranging from monomers to heptamers and even to polymers of twenty units. We have established the chemical structures of these oligomers and the monomeric units are either catechin or gallocatechin...In addition, we isolated some novel diterpenoids and a

series of simple phenols as minor constituents. As a result of biological tests we have concluded that here is no single ingredient for would healing but that the whole sap contributes to the healing process" (Phillipson, J. 1999).

It is the opinion of the Examiner, in light of the grave unpredictability in the art with regard to plant extracts, that Applicant is not enabled for any extract product as Instantly claimed. Each product obtained from an extraction from biological plant material is unpredictable in nature. Even the most skilled of artisans would need to quantify each product for constituents as well as medicinal efficacy. Considering this evidence, the skilled artisan, lacking information with regard to any other compositions which have been shown to have the effects as indicated in the Instant specification would necessarily need to perform tedious trial and error protocols without expectation of success.

Further, it is deemed that the claims are not enabled for the broad recitation of ailments. While Applicant has shown that the pawpaw fruit extract has some effect on psoriasis, scarring and pain relief when applied topically, these ailments do not provide a nexus with regard to various other skin ailments which are known including skin cancer, eczema, acne, roseacea, warts and ulcers to name a few.

The instant specification provides absolutely no guidance as to what types of skin cancer could be treated with the composition of the Instant claims, how this would

occur, or why one would expect this to occur. No nexus has been established between the treatment of psoriasis, and the treatment of potentially life-threatening malignant skin cancer. Thus, the instant specification provides no working examples and no guidance that would permit and artisan to practice the invention commensurate with the scope of the instant claims.

The prior art makes clear that treatment of skin cancer is difficult and compositions which have any therapeutic effect on skin cancer are rare; the patient often needing surgery to remove malignant tissues (see for example, Cummins, 2006 entire reference).

In re Fisher, 427 F.2d 833, 166 USPQ 18 (CCPA 1970), held that:

> "Inventor should be allowed to dominate future patentable inventions of others where those inventions were based in some way on his teachings, since such improvements while unobvious from his teachings, are still within his contribution, since improvement was made possible by his work; however, **he must not be permitted to achieve this dominance by claims which are insufficiently supported and, hence, not in compliance with first paragraph of 35 U.S.C. 112; that paragraph requires that scope of claims must bear a reasonable correlation to scope of enablement provided by specification to persons of ordinary skill in the art**; in cases involving predictable factors, such as mechanical or electrical elements, a single embodiment provides broad enablement in the sense that, once imagined, other embodiments can be made without difficulty and their performance characteristics predicted by resort to known scientific law; in cases involving unpredictable factors, such as most chemical reactions and physiological activity, scope of enablement varies inversely with degree of unpredictability of factors involved." (emphasis added)

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1, 4 and 6 are rejected under 35 U.S.C. 102(b) as being anticipated by Burchard, H. reporting for The Washington Post (1999).

Burchard, H. reporting for The Washington Post (1999) taught that pawpaw, known botanically as *Asimina triloba,* was an endogenous, fruit-bearing plant of the Eastern United states as well as Canada, often harvested for it's edible fruit as well as the fruit's medicinal and insecticidal properties (see pp. 1-2). Burchard indicated pawpaw fruit to be used in various food items such as milkshakes, baked goods, pina coladas, pie, ice cream, chutney and brandy. Burchard specifically disclosed a recipe for pawpaw fruit jam which included combining pawpaw pulp, water, applesauce, apple juice, lime juice, sugar and pectin, stirring, bringing to a boil (100 °C), 'stirring constantly' and pouring into jelly jars (see entire reference, especially page 4). Burchard additionally taught that paw paw

The term 'mild base' as recited by the claims is very broad. It is deemed that water is a 'mild base' and it is calculated as being added in the amount of about 1 to 40% of the entire composition of the jam disclosed by Burchard.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 1, 4, 5, 6 and 7 are rejected under 35 U.S.C. 103(a) as being unpatentable over Burchard, H. reporting for The Washington Post (1999) in view of Frances, F.(2000).

The teachings of Burchard, H. were discussed *supra*. Burchard did not specifically teach wherein the pH of any of the foodstuffs containing pawpaw fruit were within the claimed pH range of 'between about 7.5 to about 7.9, wherein the food composition was filtered, or frozen and then thawed and then filtered.

Frances, F.(Food Science and Technology, Second Edition, Volume 1, 2000) taught that pH adjusting agents were well-known in the food industry such as chemical leavening agents for baking (*inter alia*) (see pp. 856-857).

Although Burchard did not specifically teach that the pH's of the foods containing pawpaw fruit were within the pH range as indicated by the claims, it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art. *In re Aller*, 220 F2d 454,456,105 USPQ 233; 235 (CCPA 1955). see MPEP § 2144.05 part II A. It would have been obvious to one of ordinary skill in the art at the time Applicants' invention was made to determine all operable and optimal pH's for each individual food prepared with pawpaw fruit. It is clear that pH's of foods are routinely adjusted in the food art according to Frances, and therefore, it is deemed that pH is an art-recognized result-effective variable which would have been routinely determined and optimized in the food art.

Claims 1-4 and 6 are rejected under 35 U.S.C. 103(a) as being unpatentable over Burchard, H. reporting for The Washington Post (1999) in view of Alley, L. reporting for The San Diego Union-Tribune (2002)

The teachings of Burchard, H. were discussed *supra*. Burchard did not specifically teach wherein the composition was filtered (strained) or frozen prior to straining.

Alley, L. reporting for The San Diego Union-Tribune (2002) indicated that a corn cob jelly was prepared by boiling the ingredients for 20 min. and then straining (see p. 5)

Thus, it was clear from Alley that it was conventional to strain jelly (jam) compositions.

Although Burchard did not specifically teach wherein the food composition was filtered or frozen prior to filtering, it is deemed that first, one of ordinary skill in the art would have been motivated to filter the jam composition as disclosed by Burchard in order to obtain a jam which was less turbid. It is deemed that it was well known in the art that jams are sold with and without the solid fruit pulp. One of ordinary skill in the art would have been motivated to remove the larger amounts of fibrous pulp in the jam in order to create a jam with smoother texture. One of ordinary skill in the art would have

been motivated to freeze the composition prior to making the final jam in order to space the preparation out over time. Further, the claims are broad enough to read on wherein the fruit is heated alone with a small (1%) of a mild base such as water. The ordinary artisan would have had a reasonable expectation that freezing the water/pawpaw mixture prior to further processing would not have materially affected the composition to be used in a jam, and would have been advantageous when making large batches of the jam; that is, that the homogenization of the fruit could have been done one day, frozen, and then the rest of the process begun on the next day. Freezing foods is well known in the art and was well within the purview of the ordinary artisan at the time the invention was made.

From the teachings of the references, it is apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention. Therefore, the invention as a whole was *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references, especially in the absence of evidence to the contrary.

No Claims are allowed.

The prior art of record and not relied upon is considered pertinent to Applicant's disclosure.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Patricia Leith whose telephone number is (571) 272-0968. The examiner can normally be reached on Monday - Friday 8:30am-5:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Terry McKelvey can be reached on (571) 272-0775. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Patricia Leith
Primary Examiner
Art Unit 1655

July 16, 2007